

REMARKS

Claims 10, 11 and 14 have been amended to obviate the rejection under 35 U.S.C. 112, second paragraph.

Claims 1-8, 10, 11, 14, 16-18 and 20-34 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (4,932,965) in view of SU 513696.

The SU513696 reference relates to the joining of two tissue layers. As these suture devices use a single thread to attach to three needles, there is no indication that there is anything to distinguish between different portions of the same thread. Also at page 1, line 5 of the translation of SU 573696 states that the "device in question, like ordinary thread with a needle...". Thus, these references fail to disclose the use of a needle to receive both ends of two different sutures. The needles can be situated by the user at different positions along the thread to select the spacing necessary. This is traditionally done by sliding the thread through an eyelet on one end of the needle. These references do not disclose the need to attach two ends of different sutures to the same needle, which is clearly shown in Figure 1 of the present application where different suture strands 12, 14 enter the proximal end of needle 10, not through an eyelet.

Thus, the spacing between needles is not adjustable as taught by SU 513696.

The Office Action further indicates that the attachment of two tissue layers, as set forth in SU513696 is identical to the attachment of a prosthesis to tissue. This is not the case as clearly delineated in the present application. The needle spacing required for two tissue layers, which will heal together, is different from that required with a prosthesis, which does not involve natural wound healing. In the case of a heart valve, for example, the interface between the cuff and the tissue is prone to leakage, and requires tight placement in a small operative space with many sutures.

There is no mention of joining "biomaterials" in either of these references and there is no disclosure relating to the more complex task of mounting a prosthetic device such as a heart valve using the needle suture system of SU '696. The translation of SU '696 specifically states that "needles 2 are passing through both side(s) of incision at the portions of the tissues 3 and 4 which are to be joined." These references do not disclose or suggest attaching two separate suture strands to the same needle where the relationship between the size of the needle and the size of the threads is defined.

The Office Action indicates that the recitation of more than 3 needles relates to the discovery of an "optimum value," citing In re Boesch. Applicant disagrees, noting that the difference is not just the number of needles, but how the needles are connected to each other. Moreover, there is no motivation for providing additional needles to the device as this can add both complexity and cost. The addition of needles is, in fact, counterintuitive.

The rejection of the claims continues to remain based at least in part on Ex parte Pfeiffer, 135 U.S.P.Q 31 (1962), where it was indicated that in order to be entitled to weight in method claims, the recited structure limitations "must affect the method in a manipulative sense... ". Applicant notes that claim 5 expressly recites a plurality of more than three needles connected by different suture strands using the visual indicator to identify each strand and then secure it to another strand. Method claims 1 and 21 have been amended to further clarify how the structure affects the method "in a manipulative sense." More specifically, the indicator of the strands are used in attaching the prosthetic device to the tissue, which is not the case in the facts of Ex parte Pfeiffer. The use of a needle larger than the two attached sutures eases the insertion and reduces the risk of injury to the patient while inserting two separate strands with one needle.

Phillips does not teach or suggest the recited solution to this problem. Phillips utilizes different colors for different sutures 26, i.e., for different pairs of needles. By only using two needles connected by a single suture strand (see Fig. 2 where each suture 26 has opposite ends 28 and 30, which are the same color), Phillips does not have the problem of having the same color strands passing through the same hole. The alleged combination of Philips with SU 513696 is not obvious because there is no teaching that different color suture threads be attached to the same needle. Additionally, the SU 513696 reference does not disclose or suggest that the device is suitable for suturing a prosthetic implant. Consequently, it would not be obvious to employ a larger number of needles for securing a prosthetic implant that are interconnected by different indicators or colors. For example, nowhere is it suggested that alternating colors (claim 20) or three different colors be used in the cited references. The remaining references fail to suggest that a plurality of double stranded sutures be used for suturing a prosthetic device.

Claims 12 and 19 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the SU '696 patent and Phillips and

further in view of Alpern. Claims 9 and 15 have been rejected under 35 U.S.C. 103(a) as being unpatentable over SU '696 and Phillips '965 and further in view of Ablaza. Claim 13 has been rejected under 35 U.S.C. 103(a) as being unpatentable over SU '696 and Phillips and further in view of Ovil.

Applicants respectfully traverse these rejections of the claims. The SU 513696 reference uses a single thread (1) with 3 needles with no way to distinguish between thread segments passing through the same hole (e.g. 6 and 7). Additionally, the SU 513696 reference relates to the joining of two tissue layers (3 + 4 in the text, apparently mislabeled in the figure) and does not disclose or suggest the use of the system for suturing a prosthetic device. However, Phillips does not suggest the solution provided by the present invention. Phillips teaches that different colored threads be attached to different pairs of needles. Phillips does not teach that two different threads, that are distinguishable from each other, can be attached to the same needle.

With respect to Ovil, there is no disclosure or suggestion of how to use a suture placement device with the claimed invention in which at least three needles are connected by suture strands. Ovil teaches that "all suture 10 to be used in suturing the valve

in place are applied by knotting one of their ends and passing the suture through a slot 14...". This Ovil system cannot be used with the present invention as it requires knotting of the ends before placement.

The Office Action makes reference to In re Boesch (205 USPQ 215, CCPA 1980), however this case is not relevant to the present application where the claims recite features not found in the prior art, such as attaching two difference strands to the same needle, or attaching strands of two (or three) different colors to the same needle, of using more than three needles, of sizing the diameter of the needle based on the diameter of two strands, or of attaching the cuff of a heart valve using such a structure, or of a suture kit containing seven needles attached by six strands.

The rejection of claims is believed to be obviated in view of the above amendments and remarks. New claim 35 has have been added for consideration.

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The Examiner is encouraged to telephone the undersigned attorney to discuss any matter that would expedite allowance of the present application.

Respectfully submitted,

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